

### **III. REMARKS**

#### **Preliminary Remarks**

Claims 1 to 17 are pending in the present application, of which claims 1 and 5 are independent. Claims 1 and 5 are amended to replace the term “having a desired absorption profile” with “having the absorption profile”. Claim 18 has been withdrawn from consideration. The applicants respectfully request reconsideration and allowance of the present application.

This response is filed within the statutory period for response and is accompanied by a petition for a two-month extension of time and the appropriate fees.

#### **Patentability Remarks**

##### ***Rejection under 35 U.S.C. §112 –***

Claims 1 to 17 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants respectfully traverse in view of the preceding amendments and succeeding remarks.

Claims 1 and 5 are amended to replace “having a desired absorption profile” with “having the absorption profile”. The absorption profile is generated in step (i). Examples of absorption parameters of an absorption profile are described in the specification (see, for example, page 44, line 24 to page 45, line 7). One of ordinary skill in the art would readily recognize that the absorption profile is specific for each test sample, and therefore not indefinite. Therefore, the applicants respectfully request withdrawal of this rejection.

##### ***Rejection under 35 U.S.C. §102 –***

Claims 1, 3, 4, 7, 8, 12 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by Hale *et al.* (U.S. Pat. No. 5,607,691). The applicants respectfully traverse in view of the preceding amendments and succeeding remarks.

Claims 1 to 17 are directed to a method comprising, *inter alia*, screening a primary library or portion thereof having a plurality of test samples containing isolated compounds or isolated mixtures of compounds per test sample by generating an *in vivo*

absorption profile (claim 1) or a simulated *in vitro* absorption profile (claim 5) for each of the test samples from initial dose data and from *in vitro* bioavailability data.

In contrast, not only is there no mention in Hale *et al.* of generating either an *in vivo* or a simulated *in vitro* absorption profile from initial dose data and from *in vitro* bioavailability data but there is also no mention of using these generated absorption profiles for screening a primary compound library or portion thereof. Rather, Hale *et al.* describe a drug delivery system (see Abstract and claim 1). The Screening Procedures (columns 31 and 32) merely mention standard generic screening procedures, which are known to have many problems including ineffectiveness and inefficiency (see present application, pages 4 and 5). Contrary to the examiner's understanding, columns 44 and 45 only disclose *in vitro* testing and *in vivo* delivery of pharmaceutical agent-chemical modifier complexes, not screening using the claimed absorption profiles.

In other words, Hale *et al.* do not teach every element of claims 1, 3, 4, 7, 8, 12 and 13 and therefore cannot anticipate these claims. Therefore, the applicants respectfully request withdrawal of this rejection.

*Rejection under 35 U.S.C. §103 –*

Claims 1 to 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hale *et al.* taken with Yang *et al.* (Pharmacokinetics, Introduction to Biochemical Toxicology, Hodgson and Levi (Eds.), Appleton & Lange, Norwalk, CT, 1994, pp. 49-73) and in view of Jacobson *et al.* (U.S. Pat. No. 5,773,423). The applicants respectfully traverse in view of the preceding amendments and succeeding remarks.

As noted above, there no mention in Hale *et al.* of generating either an *in vivo* or a simulated *in vitro* absorption profile from initial dose data and from *in vitro* bioavailability data but there is also no mention of using these absorption profiles for screening a primary compound library or portion thereof. Yang *et al.* and Jacobsen *et al.* do not make up the deficiencies of Hale *et al.* Neither Yang *et al.* nor Jacobsen *et al.* teach or fairly suggest the generation and use of an *in vivo* or a simulated *in vitro* absorption profile for screening compounds. Thus, the combination of Hale *et al.* with Yang *et al.* and Jacobsen *et al.* does not teach or suggest all the claim limitations.

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The applicants respectfully submit that claims 1 to 17 are not unpatentable over Hale *et al.* taken with Yang *et al.* and in view of Jacobson *et al.* and request withdrawal of this rejection.

### III. CONCLUSION

In view of the amendments and remarks above, the applicant respectfully submits that this application is in condition for allowance and request favorable action thereon.

In the event this paper is not timely filed, the applicant hereby petitions for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper, referencing Attorney Docket No. 108910-00072.

Respectfully submitted,

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